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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,013	06/22/2005	Jochen Knolle	2918-109	3594

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
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SUITE 800
WASHINGTON, DC 20005

EXAMINER

CHU, YONG LIANG

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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11/06/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/540,013

Applicant(s)

KNOLLE ET AL.

Examiner

Yong Chu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-87 are currently pending in the instant application and are subject to the following lack of unity requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-87 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Due to lack of core structure and the numerous and widely divergent variables in the compound of formula (I), for example A, B, C, D, Ra, L1, K, L2, R^b, R^c, R^d, R^e, t, R⁹, R², R³, R⁴, R^h, R^j, R^k, U, W, R¹⁰-R²¹, Rⁿ, R^o, Y, Z, R^x, etc., the general formula I contains various distinct special technical features, and therefore the inventions are lack

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of unity. For this reason, further restriction is required. A precise listing of inventive groups cannot be made. The following groups are exemplary, and may be subject to further restriction:

Group I: Claims 1-37 and 87 are drawn to a compound of formula (I) A-B-E-D, according to Claim 1. This group is subject to further restriction if elected.

Group II: Claims 38-84 are drawn to use of a compound of formula (I) according to Claim 1 for manufacture of a medicament. This group is subject to further restriction if elected. Applicant is reminded that the "use" claim style is an E.U. claim style, and does not comply with U.S. practice. An appropriate amendment is suggested.

Group III: Claims 85-86 are drawn to a method of using the said compound for the treatment of various diseases or disorders. This group is subject for further restriction if elected.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The elected group is subject to further restriction.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose or suggest a single by identifying another specific embodiment, i.e. another group, not listed as the exemplary groups of the invention and examiner will endeavor to group the same. ***Applicant also needs to elect a single compound as the elected species for initial search purpose.***

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The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature evidenced by formula I' with numerous and widely divergent variables in the compound of formula (I').

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

New Rules on Patent Examinations

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

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If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

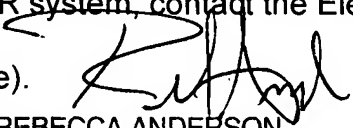
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed Yong Chu whose telephone number 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Yong Chu, Ph.D.
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